Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jul 2026

Clinical trial of weight loss programs in obese patientswith majoneh etrifel saqir in comparison with placebo

Protocol summary

Summary

The study is a randomized double-blind clinical trial for comparing the effect of herbal medicine etrifel saqir with placebo. Patients with a BMI more than 30 and age range 16-60 years old will be included. The study aim is gradual weight loss that will maintain ideal body weight. In this study etrifel saqir drug (etrifel saqir composed of Terminalia chebula and Phyllanthus emblica and Terminalia bellerica; component equal weight to mixed with, almond oil or cow fat, honey Formation Concoction.) is investigated. In this clinical trial, 60 participation (30 patients receiving the drug group and 30 in the control group) according to random allocation inclusion & exclusion criteria will be recruited. for duration of three months. The medication will be used as much as one teaspoon twice a daily. The control group received placebo twice a daily. All the participants will complete the consent form. Probable side effects will be assessment during intervention, and assessment of Primary outcome are control at base line, 4weeks, 8 weeks and 12 weeks after intervention . Primary outcome are: weight, waist and hip circumference and secondary outcome are include Fasting blood glucose, blood lipid profile and liver enzymes[CBC, FBS, 2HPP(with 100 gram Glocose), Insuline(Fasting), Cratinine, PT, aspartate aminotransferase (SGOT), Alanine Aminotransferase (SGPT), Alk Phos, Cholestrol, Triglicerid , high-density lipoprotein (HDL), low- density lipoprotein (LDL), Uric acid, hemoglobin(HGA1C)] assessment at entry and end of intervention . In addition to completing On arrival the temperament organic forms and General temperament of intervention . and Nutrition counseling and completion of a two-day food records and supply information in the entry and end of study period. And study period is three months.Concoction twice a day every time the size of a teaspoon will use.The control group received placebo twice a day can. every time the size of a teaspoon will use. In addition to completing the consent form on arrival and temperament organic forms and general temperament and side effects completion at Before intervention, 4 weeks after intervention,8 weeks after intervention, 12 weeks after intervention. Primary outcome measured weight and waist circumference and hip circumference and secondary outcome measured include Fasting blood glucose and blood lipid profile and liver enzymes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104206237N1**
Registration date: **2011-06-21, 1390/03/31**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-06-21, 1390/03/31

Registrant information

Name

Dr. Seyed Hamid Kamali

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

Phone

+98 21 4420 6157

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Recruitment status

Recruitment complete

Funding source

Shahed university

Expected recruitment start date

2011-06-21, 1390/03/31

Expected recruitment end date
2012-06-20, 1391/03/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical trial of weight loss programs in obese patientswith majoneh etrifel saqir in comparison with placebo

Public title
The efficacy and safety of etrifel saqir in obese patients with placebo
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteria: Having BMI more than 30; age between 16 to 60 years old;(Between50 to 60 with normal ECG) inform consent signed by the patient; those who can over the next three months five times refer for take drugs and laboratory examination and Waist circumference > 102 cm (men) or > 88 cm (women) Exclusion Criteria: Heavy Smoking(More than twenty cigarettes per daily); pregnancy; patients with coronary heart vascular disease; diabetes mellitus; patients with proven malignancy, asthma, chronic cough, chronic lung inflammatory and bowel disease, fever of unknown origin; patients with a history of chronic kidney and liver disease(Exception fatty liver and not including obesity, allergies, skin problems, or occasional GERD or IBS symptoms); obesity due to endocrine (hypothyroidism, uncontrolled disease) disease; genetic obesity syndrome; patients treated recently with sliming drugs; patients in the last three months, have been taken thin regimes; having psychological problems(psychiatric disorder (including recent diagnosis depression, bipolar disorder, and anxiety determined by self-report during screening .(diagnosis in last three month); alcohol consumption; persons with weight loss after surgery and receiving corticosteroid or Immunosuppressive medications
Age
From **16 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahed University
Street address
Keshavarz bolevard, Abdollahzadeh st.,Shahed Medical University
City
Tehran
Postal code
141563511
Approval date
2011-05-31, 1390/03/10
Ethics committee reference number
112251/4

Health conditions studied

1

Description of health condition studied
Obesity
ICD-10 code
E65
ICD-10 code description
Obesity due to excess calories

Primary outcomes

1

Description
Body Mass Index
Timepoint
Monthly
Method of measurement
Calculation of height and Weight

2

Description
Waist circumference
Timepoint
Monthly
Method of measurement
Metric

3

Description
Weight

Timepoint
Monthly
Method of measurement
Scale

4

Description
Volume hip circumference
Timepoint
Before intervention, 4weeks after intervention,8 weeks after intervention, 12 weeks after intervention
Method of measurement
Metric

Secondary outcomes

1

Description
Fasting blood glucose
Timepoint
Before intervention, 12 weeks after intervention
Method of measurement
Laboratory measurement method auto analyzer

2

Description
Blood pressure
Timepoint
Monthly
Method of measurement
Blood pressure barometer

3

Description
Serum Triglycerid
Timepoint
Before intervention, 12 weeks after intervention
Method of measurement
Laboratory measurement method auto analyzer

4

Description
Serum low density lipoprotein level
Timepoint
Before intervention, 12 weeks after intervention
Method of measurement
Laboratory measurement method auto analyzer

5

Description
Serum High Density Lipo protein(HDL)
Timepoint
Before intervention, 12 weeks after intervention
Method of measurement
Laboratory measurement method auto analyzer

6

Description
Serum Cholestrole
Timepoint
Before intervention, 12 weeks after intervention
Method of measurement
Laboratory measurement method auto analyzer

7

Description
Alanine transaminase
Timepoint
At the begining and 12th week
Method of measurement
Laboratory measurement method auto analyzer

8

Description
Aspartate aminotransferase
Timepoint
Before intervention,12 weeks after intervention
Method of measurement
Laboratory measurement method auto analyzer

9

Description
Serum Creatinin
Timepoint
Before intervention,12 weeks after intervention
Method of measurement
Laboratory measurement method auto analyzer

10

Description
Serum Alkaline Phosphatase
Timepoint
At the begining and 12th week
Method of measurement
Laboratory measurement method auto analyzer

Intervention groups

1

Description
Intervention group: Drug majoneh etrifel saqir composed of Phyllanthus emblica, Terminalia chebula ret, Terminaliacitrina roxb, Myrobalanus nigrae, Terminalia bellerica, a component inside almond oil and Honey. Volunteers will take a teaspoon concoction twice a day for three months.
Category
Treatment - Drugs

2

Description
Control group: Volunteers will take a teaspoon

concoction of placebo twice a day for three months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Salamt clinic, Shahed University

Full name of responsible person

Dr. Seyyed Hamid Kamali

Street address

Keshavarz bolevard, Italia st., Near Mostafa Khomeini Hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Dr. Heshmat

Street address

Keshavarz boulevard, Abdollahzadeh st., Shahed Medical University

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahed University

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tradtional institue

Full name of responsible person

Seyed Hamid Kamali

Position

PhD candidate of TraditionalL Medicine

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty